

Sulcoflex Supplementary Intraocular Lenses (IOLs) Patient Information





About supplementary intraocular lenses

This leaflet is intended to provide you with helpful information about a product used during eye surgery called a supplementary Intraocular Lens (IOL).

If it has been recommended that you have a supplementary IOL implanted then it is likely that you have already had eye surgery and an IOL placed inside your eye. This IOL would have been a small acrylic lens that replaced the natural crystalline lens in your eye that focuses incoming light onto the back of the eye (the retina). The crystalline lens was removed during surgery, typically following the formation of a cataract.

A supplementary IOL is designed to help with any adjustment or enhancement to your vision needed or desired after your original eye surgery. Supplementary IOLs are implanted as part of a second surgical procedure in front of your primary IOL, in a space within the eye called the ciliary sulcus. The ciliary sulcus is located just behind the iris, which controls how much light is let into your eye. Supplementary IOLs are incredibly thin, with an advanced optic that adjusts or upgrades the power of your primary IOL to improve your vision. They can be implanted any time after your original eye surgery, and you do not need to have a Rayner primary IOL inside your eye in order to have a Rayner Sulcoflex supplementary IOL implanted. In the unlikely event that you experience a problem with your vision after implantation of a supplementary IOL then it can be removed, replaced or even upgraded at any time.

The supplementary IOL being used in your eye surgery is manufactured by a company called Rayner, based in the United Kingdom. Founded in 1910, Rayner supplies eye products to over 80 countries worldwide.

This patient information leaflet covers the following Rayner supplementary IOLs:

- Sulcoflex Aspheric
- Sulcoflex Toric
- Sulcoflex Trifocal



The supplementary IOL is packaged in a sterile blister pack and will be loaded into a single use injector device. Your surgeon will inject the supplementary IOL through a tiny incision that is made in your cornea (the clear front part of your eye), typically only 2.2 mm to 2.8 mm wide. The incision will selfheal after your surgery.

Following your eye surgery, the supplementary IOL will provide you with improved vision. Your vision post-surgery is dependent on the supplementary IOL model implanted. The following table indicates the high-quality and spectaclefree vision that can be expected after your eye surgery; however, supplementary IOL suitability is based on your eye health, lifestyle and other factors which will have been discussed with your surgeon:

	Near vision Reading, writing, using your smartphone or performing close work	Intermediate vision Computer work, cooking or doing anything at arm's length (40 cm to 100 cm)	Distance vision Daily activities such as cycling, driving, watching TV or attending events	Astigmatism correction ¹
Sulcoflex Aspheric			1	
Sulcoflex Toric			√	✓
Sulcoflex Trifocal ³	√	1	<i>√</i>	

1. Astigmatism

Astigmatism is an imperfection in the curvature of the cornea resulting in distorted or blurred vision at all distances. The condition is very common and occurs when the shape of the cornea is not spherical or regular. Simply, the curvature of the cornea can be described as the curvature of a rugby ball (or American football) which is varied over the surface instead of having a constant radius like the curve of a spherical football.

If the corneal curvature is irregular, the light entering the eye is not correctly received by the retina, causing blurred and distorted vision, regardless of the distance at which the objects are located. Astigmatic vision lacks precision, and it is difficult to distinguish clearly between certain shapes and details.

An astigmatism is usually accompanied by myopia (near-sightedness, when close objects look clear but distant objects appear blurred) or hyperopia (farsightedness, when distance objects look clear, but close objects appear blurred).

The surface of a toric supplementary IOL is specifically designed to overcome the effect of your astigmatism and provide you with clearer vision.

2. Trifocal IOLs

Most IOLs and supplementary IOLs only provide a single focal point (typically for distance vision) which means that spectacles need to be worn for most activities requiring near or intermediate vision.

Sulcoflex Trifocal is one of the most advanced supplementary IOLs available today, using patented optics that give you the opportunity to increase independence from wearing glasses for the majority of everyday activities. When implanted on top of your primary IOL, Sulcoflex Trifocal uses diffractive step technology made up of 16 rings that split the incoming light in order to provide near, intermediate and distance vision. The optics transmit 89% of available light to the retina.

Diffractive step technology is designed to provide you with spectacle free near, intermediate and distance vision; however, potential side effects associated with the implantation some of diffractive IOLs are:

- Decrease in contrast
- Halos when driving at night
- Visual disturbances including halos and glares, which decrease with time (neuroadaptation)



Risks and side effects

Implantation of a supplementary IOL is a safe and effective surgical procedure to improve your vision. However, as with all surgical procedures, there are risks as well as benefits. The outcome of intraocular lens implantation cannot be guaranteed and it is important to be aware of possible effects on vision after surgery, which your surgeon will discuss with you.

Potential complications of cataract surgery are:

- Secondary glaucoma
- IOL replacement or extraction
- Precipitates
- Reduced vision
- Vitreous herniation

- Excessive intraoperative vitreous loss
- IOL decentration
- Secondary membrane
- Expulsive haemorrhage
- IOL dislocation and subluxation
- Retrolenticular membrane
- Corneal oedema
- Endophthalmitis and panophthalmitis
- Retinal detachment
- Corneal dystrophy
- Haemorrhage
- Iris atrophy
- Pupillary block
- Cystoid macular oedema
- Severe ametropia and aniseikonia
- Iridocyclitis and hyalitis
- Deviation from target refraction
- Fibrin reaction



Your Your vision world

Additional information

Electromagnetic compatibility

Rayner supplementary IOLs are considered safe for magnetic resonance imaging (MRI), and do not pose an increased risk during diagnostic investigation or therapeutic treatment.

Product lifetime

Rayner supplementary IOLs are single piece optical devices, manufactured from Rayacryl (hydroxyethyl methacrylate/methyl methacrylate copolymer with UV blocker). A product lifetime of twenty years has been assigned to these devices, corresponding to the shelf-life of the product, typical age of the patient and typical life expectancy.

Post-surgery checks

Your surgeon will advise on the frequency of vision checks after your eye surgery, and you may be referred back to your regular optometrist/optician.

What shall I do if I experience a problem related to my supplementary IOL?

If you have a serious incident during or after your surgery that occurs in relation to the supplementary IOL then it should be immediately reported to Rayner (IOL manufacturer) and to the Therapeutic Goods Administration (Australian Government's regulatory body) using the following contact details:

- Rayner: feedback@rayner.com
- •Therapeutic Goods Administration: https://www.tga.gov.au







Rayner Intraocular Lenses Limited Rayner Sulcoflex supplementary IOL Patient Information Leaflet, November 2021 – Version 1.0 EC 2021-80 AU 11/21

